UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOANNE NORIEGA, on behalf of herself and all others similarly situated,

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

Case No.:

COMPLAINT

Plaintiff Joanne Noriega, on behalf of herself and all others similarly situated ("Plaintiffs"), by and through her undersigned counsel, Denlea & Carton LLP and Kravit Smith LLP, states for her Complaint against Abbott Laboratories ("Abbott" or "Defendant"), as follows:

PRELIMINARY STATEMENT

1. Malnutrition in children remains one of the world's greatest tragedies. "Good nutrition is the bedrock of child survival, growth, and development. Well-nourished children are better able to learn, play and participate in their communities. They are also more resilient in the face of illness and crisis."[1] While severe stunting (the failure to grow taller due to malnourishment) and wasting (children who are dangerously thin for their height due to malnutrition and have weakened immune systems and an increased risk of disease and death) have decreased globally by a third since 2000, malnourishment remains one of the world's most dire challenges.[2]

2. Liquid-based Oral Nutritional Supplements ("ONS") were originally formulated to support the enhanced needs of under- and malnourished children in the Third World, but these supplements are now available to the general public and have become enticing "solutions" for parents who are acutely aware of the social and clinical implications of small body size. But "[s]imply bolstering growth in response to perceptions that 'bigger is better' is not without risk, and the long-term health ramifications of feeding supplements are becoming increasingly clear. Concerns about increasing weight without increasing skeletal size have been raised amongst human growth specialists since 1959."[3]

3. Moderate and severe stunting and wasting remains a predominantly Third World problem that has been virtually eradicated in the United States, which reports the lowest incidence of wasting (none) and moderate to severe stunting (3%) among the world's 195 countries and territories. By comparison, 48% of children in India suffer from moderate to

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1 https://www.unicef.org/nutrition

2 *Id.*

3 Lampl, M., et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*. Healthcare (Basel). 2016 Nov 12;4(4):84. doi: 10.3390/healthcare4040084. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198126/.

severe stunting and 43% suffer from moderate to severe wasting.[4]

4. While children in the United States do not need or benefit from ONS, Abbott has aggressively marketed its PediaSure Grow and Gain line of "nutrition" drinks ("PediaSure") to parents of picky eaters who are shorter than their peers. As a consequence, Abbott garners yearly revenues exceeding $250 million from its sales of PediaSure — just a flavored sugar and milk-based drink that contains vitamins — which is not a cure for shortness.

5. Without any scientific support, however, Abbott claims that PediaSure is "clinically proven to help kids grow" (the "Clinically Proven Claim") and its marketing makes crystal clear (as further alleged below) that "grow" means to increase height, not some other dimension. (cf. "gain" as regarding weight claims). Indeed, even Abbott's own financed clinical studies — studies that are not disclosed by Abbott in its marketing materials — confirm that PediaSure does not increase height-to-age or height-to-weight in children. In short, not only does Abbott lack any support for its Clinically Proven Claim, it knows from its own studies that its Clinically Proven Claim is false and misleading.

6. As the National Advertising Division of BBB National Programs (the "NAD")[5] has repeatedly stated, however, representations that a product's efficacy has been "clinically proven" must closely match the underlying evidence because they are a promise that there is

[4] UNICEF Report, *"Improving Child Nutrition: The achievable imperative for global progress"*, April 2013. Available at https://data.unicef.org/resources/improving-child-nutrition-the-achievable-imperative-for-global-progress/.

[5] The NAD is an independent system of self-regulation established by the advertising industry in 1971 and designed to build consumer trust in advertising. It reviews national advertising in all media in response to third-party challenges or through inquiries opened on its own initiative. The NAD's decisions set consistent standards for advertising truth and accuracy, delivering meaningful protection to consumers and leveling the playing field for business. An advertiser's failure to participate in the NAD's review of its advertising and/or failure to comply with the NAD's recommendations and decision results in the matter being referred to the appropriate regulatory agency, which is typically the Federal Trade Commission. NAD referrals receive priority treatment from the Federal Trade Commission.

scientific evidence that establishes the truth of the claim. Such a claim conveys an especially strong message to consumers.

7. Based on Abbott's deceptive Clinically Proven Claim, Plaintiff and consumers like her purchased PediaSure products that they believed were clinically proven to increase height, and they purchased PediaSure with a reasonable expectation as to their premium quality and efficacy. Moreover, Plaintiff purchased PediaSure notwithstanding the fact that similar meal replacement products, which appropriately are not marketed as clinically proven to increase height, were and are available from other manufacturers for much less money. Accordingly, Plaintiff and her fellow class members have been injured because they purchased PediaSure products that they would not have otherwise purchased and/or they paid a premium for PediaSure ONS products that were purportedly clinically proven to increase height but were, in actuality, not clinically proven to be an effective means for increasing height. Simply put, Plaintiff and members of her class were deceived by Abbott's fraudulent marketing of PediaSure and Abbott profited from that deception at Plaintiff's and her class members' expense.

8. By way of this action, Plaintiff seeks to put an end to Abbott's deceptive marketing campaign built upon the premise that PediaSure is "clinically proven" to increase height and to obtain the financial redress to which Plaintiff and her class members are entitled.

THE PARTIES

9. Plaintiff Joanne Noriega is an individual who resides in Bronx, New York.

10. Defendant Abbott Laboratories is an Illinois corporation with its principal address at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.

11. Abbott manufactures, packages, markets, distributes, and sells PediaSure Grow and Gain bottles, cans, and mixes (the "PediaSure Products") both online directly to consumers

and through other online and brick-and-mortar retail stores, such as Sam's Club, Amazon, Target, Rite Aid, Walgreens, CVS, and grocery stores. Abbott also manufactures, packages, markets, distributes, and sells a product called "PediaSure Sidekicks" which is similar to the other PediaSure Products but has less sugar and fat and does not make the Clinically Proven claim. PediaSure Sidekicks are, therefore, not the subject of Plaintiff's claims and are not included in the definition of PediaSure Products for purposes of this Complaint. In fact, separate deceptive marketing claims relative to PediaSure Sidekicks were specifically dealt with by the New York Attorney General in 2013. Abbott was fined and required to cease its false advertising.[6]

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because (1) the amount in controversy exceeds the sum or value of $5,000,000.00, exclusive of interest and costs, and (2) the named Plaintiff and Defendant are citizens of different states. 28 U.S.C. § 1332(d)(2)(A).

13. The Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), as the parties are diverse and the amount in controversy exceeds the requisite threshold.

14. This Court may exercise jurisdiction over Abbott because Abbott has sufficient minimum contacts in New York and purposely avails itself of the markets within New York through the promotion, sale, marketing, and distribution of its products, thus rendering jurisdiction by this Court proper and necessary.

[6] *A.G. Schneiderman announces settlement with maker of PediaSure Sidekicks Supplement for misleading advertising*. https://ag.ny.gov/press-release/2013/ag-schneiderman-announces-settlement-maker-pediasure-sidekicks-supplement

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claim occurred within this judicial district and because Abbott has marketed and sold the products at issue in this action within this judicial district and has done business within this judicial district.

CHOICE OF LAW

16. New York law governs the state law claims asserted herein by Plaintiff Joanne Noriega and the New York class she seeks to represent.

17. New York has a substantial interest in protecting the rights and interests of New York residents against wrongdoing by companies that market and distribute their products within the State of New York.

FACTUAL BACKGROUND

18. Abbott is an American multinational medical devices and health care company with headquarters in Abbott Park, Illinois, United States. The company was founded by Chicago physician Wallace Calvin Abbott in 1888 to formulate drugs. Today, it sells medical devices, diagnostics, branded generic medicines and nutritional products. Among its nutritional products, Abbott manufactures and sells the PediaSure Products that generate revenues of over $250 million each year in the United States and an estimated $15 million each year in New York State alone. In 2022, Abbott generated global revenues in excess of $43 billion.

I. Due to the Premium Consumers are Willing to Pay for Products That are Backed by Science, Manufacturers Routinely Misrepresent That Their Products Have Been Scientifically Proven to be Effective.

19. Consumers who are concerned about health are particularly vulnerable targets for unscrupulous manufacturers and advertisers. Such consumers are willing to pay a premium for health products that are scientifically proven to be effective. In an overcrowded marketplace where beneficial health claims are ubiquitous, being able to demonstrate the efficacy of a product

is critical. Unsurprisingly, in order to differentiate their products and gain a competitive edge, manufacturers and advertisers routinely mislead consumers by claiming that the efficacy of their products is backed by science (*i.e.*, "establishment claims"), when, in fact, it is not. Accordingly, Courts are wary of claims by manufacturers that their product has been scientifically proven to be effective, when those claims are false.

20. Establishment claims are held to the highest standard of proof because the message that they convey to consumers is especially strong. As the NAD has repeatedly stated, "[e]stablishment claims are powerful claims that should be reserved for products that have clinical human testing as support."[7]

21. An advertiser's health-related claims about the efficacy of a product must "be supported with 'competent and reliable scientific evidence,'" which the Federal Trade Commission (the "FTC") defines as "'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'"[8] As the FTC has stated, "well-controlled human clinical studies are the most reliable form of evidence."[9]

II. Abbott Espouses the Efficacy of the PediaSure Products for Increased Height.

22. PediaSure was launched in or about 1987 and registered its "Grow and Gain" name for trademark protection in 2015. Today, PediaSure is a market leader in nutritional supplements for children. PediaSure is marketed for children ages 2 to 13.

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[7] *See, e.g.*, NAD Case Report #6952 (Aug. 27, 2021) at 10. Available here NAD Case Report 6952.pdf.

[8] FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B), at https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry

[9] FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B)(2), at https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry

23. PediaSure makes the Clinically Proven Claim on all the front labels of each of the PediaSure Products, as well as on the PediaSure.com website, resellers' websites and in TV and print marketing. A universal theme in PediaSure marketing is the image of a giraffe next to a graphic of a ruler, thereby conveying the clear message that PediaSure helps a child grow taller.

24. Although PediaSure also claims to help with weight gain, that claim is not the subject of Plaintiff's claims here. It is self-evident that consumers would be far less willing to purchase the premium priced PediaSure, if it was marketed solely for gaining weight, and if that claim was not accompanied by the height increase claim. Significantly, as will be demonstrated

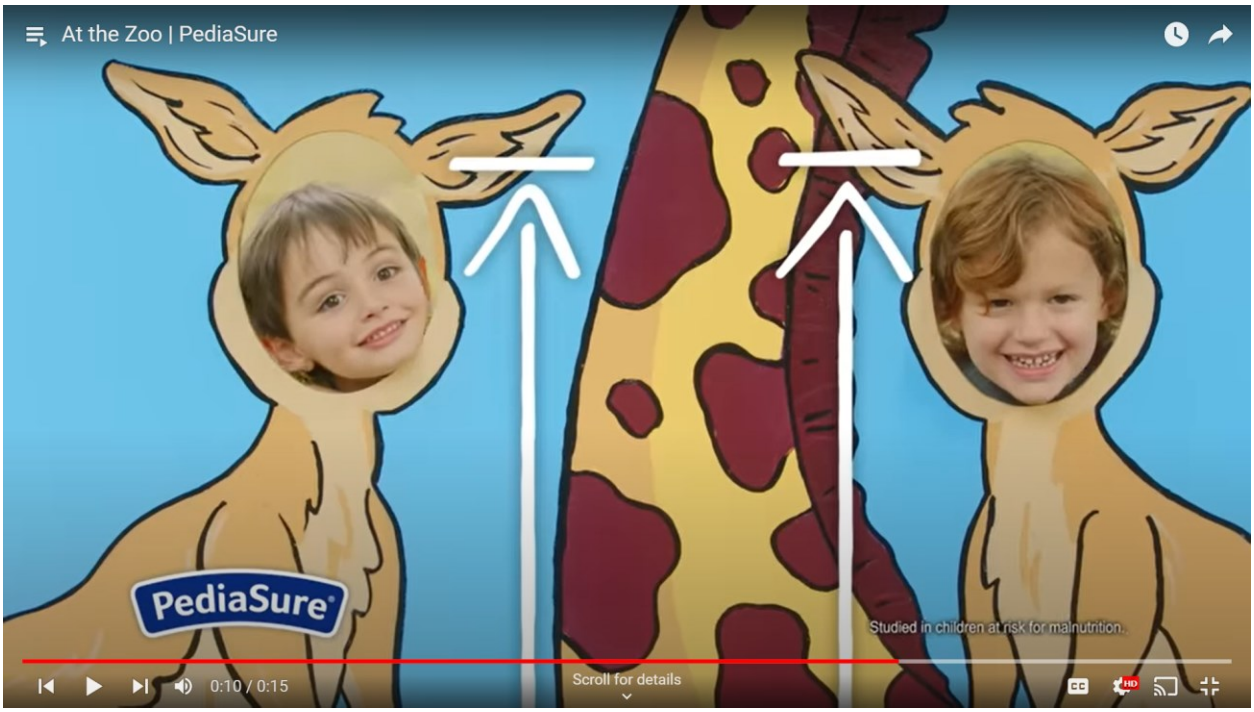
herein, the vast majority of the PediaSure advertising claims relate almost exclusively to increased heights, with barely a mention of weight gain.

25. Abbott has obviously recognized that the height increase claim must be the predominant focus on the marketing of PediaSure and that recognition is evident in the marketing materials, starting with the ubiquitous giraffe and ruler image on every PediaSure Product label.

26. The focus on PediaSure's claim to increase height is carried over to the PediaSure.com website, and makes clear the "clinically proven to help kids ***grow***" (emphasis supplied) claim relates to growth in height.

27. Similarly, PediaSure's TV and video marketing emphasizes Abbott's claim that PediaSure will lead to a child's height increase:

The voice over in the "At the Zoo" spot states "Being a mom means I notice everything, like when he has fallen behind on height and weight." The ad then shows the smaller boy being lifted up to reach the same height as his bigger brother in the cutout next to the giraffe.



28. In the "School" spot[10], a shorter boy gets up on his toes to reach his taller classmates:

[10] https://www.youtube.com/watch?v=NHvi06MVg1E&list=PLQj6HLlAIBcy9a0FEERS-rOso1abdJvLw&index=3


LAPS2024000H 06 School English Web 16x9
PediaSure
Clinically proven to help kids grow. Studied in children at risk for malnutrition.
Non-GMO. Ingredients not genetically engineered.
Nutrients for immune support: Protein, Vitamins A, C, D & E, Selenium and Zinc
0:01 / 0:06
Scroll for details


LAPS2024000H 06 School English Web 16x9
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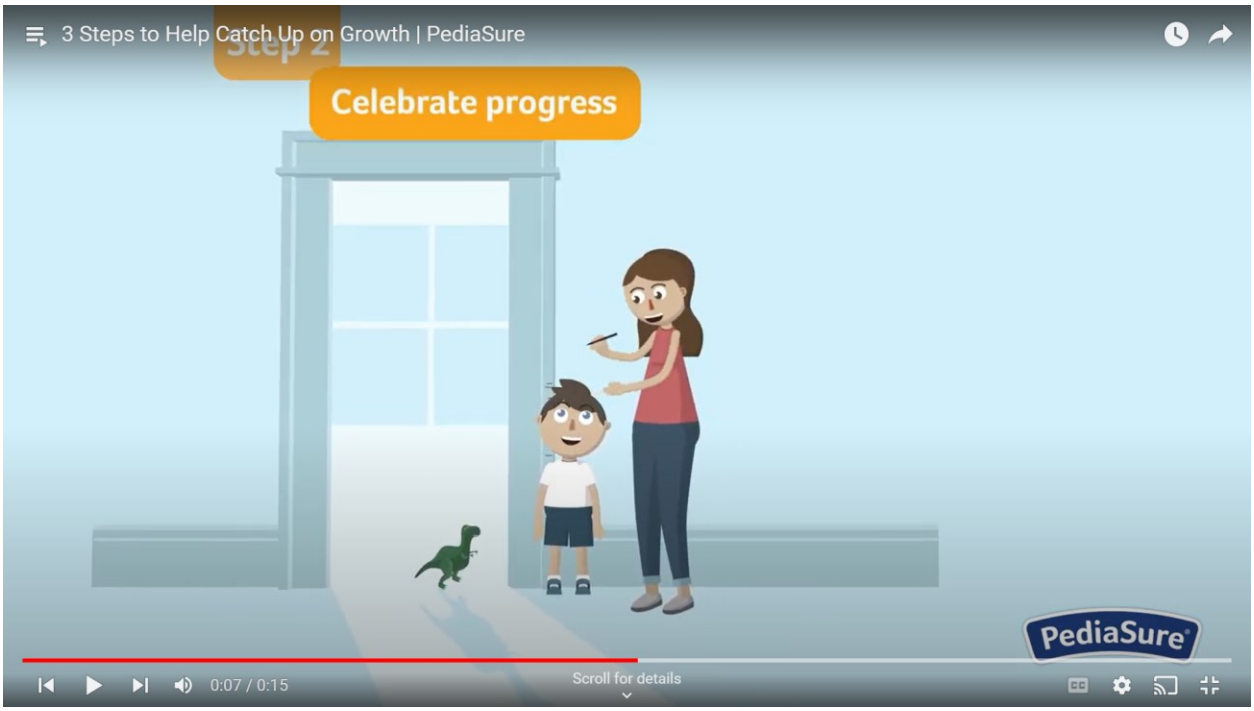
0:02 / 0:06
Scroll for details

29. PediaSure's "Nutrients Kids Need to Help Catch Up on Growth" spot[11] similarly focuses on increased height, not weight, and reflects, like all other ads, the Clinically Proven Claim:

30. PediaSure's "3 Steps to Help Catch Up on Growth" spot[12] again focuses on height increase rather than weight increase:

[11] https://www.youtube.com/watch?v=5ZvgEpQ42lo&list=PLQj6HLlAIBcwkhZKCkV7sz6KM26AOAEna

[12] https://www.youtube.com/watch?v=TovaTetVoP8&list=PLQj6HLlAIBcwkhZKCkV7sz6KM26AOAEna&index=2



III. The Clinically Proven Claim is False and Designed to Deceive Consumers.

31. Reasonable consumers understand the Clinically Proven Claim to convey that each PediaSure Product on which it appears has been clinically proven to help increase a child's height.

32. Abbott's Clinically Proven Claim, however, is patently false and misleading with respect to each of the PediaSure Products on which it appears because, among other things, the purported clinical studies and reports cited by Abbott on the PediaSure website do not support its Clinically Proven Claim.

33. Specifically, Abbott lists six "references" on its website.[13] American consumers are led to believe that Abbott studied children comparable to their own, and that they could rely upon that research as predictive of what their child's experience would be after consuming PediaSure. Nothing could be further from the truth. Significantly, none of those studies

[13] https://pediasure.com/nutrition-drinks-for-kids/grow-gain-nutrition-shakes

involved children in "First World" countries, such as the United States, where the incidence of stunting and wasting caused by malnourishment is virtually non-existent.

34. Abbott clearly recognizes the incongruity of marketing an ONS designed for, and studied in, starving children in the Third World, so it buries that fact as deeply as possible — as deceptive marketers have done from time immemorial — in microprint. Each Clinically Proven Claim on the label of the PediaSure Products and the marketing of the PediaSure Products is accompanied by a microscopic asterisk and an even smaller delphic statement, "Studied in children at risk of malnutrition," which cannot even be seen without lifting up the bottom on the bottle.


Pedia
Grow & Gain
WITH
Immune Support
Clinically Proven to Help Kids Grow
DHA
OMEGA-3
27
VITAMINS & MINERALS
7g
PROTEIN
chocolate
NATURAL & ARTIFICIAL
8 FL OZ

Abbott nowhere explains what the "risk of malnutrition" means in this context, but it is abundantly clear that Abbott does not want an American consumer to see the microscopic disclaimer because, presumably, an American consumer would know that their child is not at risk of malnutrition. Significantly, the subjects of Abbott's various studies were not "at risk" of malnutrition, they were tragically and chronically suffering from active malnutrition, with attendant co-morbidities.

35. Additionally, three studies (two studies and one follow-up study) financed by Abbott and authored by Abbott researchers that were conducted ***after*** the six studies cited on the PediaSure website, confirmed that there had been no evidence that using PediaSure led to an increase in a child's height-to-age or height-to-weight. None of those three studies are cited by Abbott on the PediaSure website. It is self-evident that Abbott intentionally and misleadingly omitted those studies because they directly refute the Clinically Proven Claim.

36. The first omitted study (again, conducted ***after*** the studies cited on the PediaSure website), Ghosh, A., et al., *Effect of oral nutritional supplementation on growth and recurrent upper respiratory tract infections in picky eating children at nutritional risk: a randomized, controlled trial,*[14] (hereinafter, the "Abbott 2018 Study"), discloses that "Abbott Nutrition provided funding for the present study and was responsible for the study design, monitoring, data analysis, and preparation and submission of the manuscript" and three of the authors were Abbott employees. Notwithstanding that the study was funded, designed and the manuscript prepared by Abbott employees, the study concluded: ***"We did not observe any significant improvement in height within each treatment group or between the two groups, similar to a previous study."*** Further, ***"In contrast (to weight), the change in height was not significantly different between the two groups across all assessment time points"***.[15]

37. There was a follow-up to the Abbott 2018 Study, which reinforced the earlier negative finding.

> The SDC and DC groups showed a decline in HAP [Height for Age Percentile] from the onset of the study, but this decline was significantly slower in the SDC group compared with the DC group during the intervention phase from Day 1 to Day 90. Despite self-supplementation from Day 90 to Day 210, there was no significant difference in the rate of

[14] J. Int. Med. Res. 2018 Jun; 46(6): 2186–2201 doi: 10.1177/0300060518757322. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6023057/.

[15] The "previous study" referred to in the Abbott 2018 Study is one of the six references on the PediaSure website.

> HAP decline between the SDC-ONS and SDC No-ONS subgroups, although there was a marginally larger decline in the DC No-ONS subgroup compared with the DC-ONS subgroup. The decline in HAP observed throughout the study groups and subgroups occurred despite an increase in height from Day 1 to Day 210. This lack of improvement in HAP may be attributed to the relatively short study duration of supplementation (Day 1 to Day 90), inconsistent self-provision of ONS during the follow-up phase (Day 90 to Day 210), and lower volumes of ONS consumed. These factors could be reasons why we did not observe an improvement in HAP, especially among the supplemented group."[16]

38. The Ghosh researchers omitted the most obvious and self-evident reason for the failure to "observe an improvement in HAP," namely that PediaSure Grow and Gain does nothing to increase height. There are known substances that can increase height in humans, including anabolic steroids and gonadotropin releasing hormone analog.[17] Yet PediaSure's sugar, cocoa powder, red dye #3, and cellulose gel, do not number amongst effective and medically recognized growth agents.

39. The third study omitted by Abbott from the PediaSure website, Khanna, D., et al., *Oral Nutritional Supplementation Improves Growth in Children at Malnutrition Risk and with Picky Eating Behaviors*,[18] (hereinafter the "Abbott 2021 Study"), was funded by Abbott and the lead author was employed by Abbott. Despite the fact that the Abbott 2021 Study was entirely a product of Abbott's research, the Abbott 2021 Study concluded, among other things, two things that completely undercut the PediaSure Clinically Proven Claim: (1) "ONS [the PediaSure oral nutritional supplement] groups showed a trend toward greater height gain when compared to DC [dietary counseling] only group, but the differences were not significant within the study

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[16] Ghosh, et al., *Continuation of oral nutritional supplementation supports continued growth in nutritionally at-risk children with picky eating behaviour: A post-intervention, observational follow-up study*, J Int Med Res. 2018 Jul;46(7):2615-2632. Available at https://ncbi.nlm.nih.gov/pmc/articles/PMC6124283/.

[17] Satoh M, Yokoya S., *Anabolic steroid and gonadotropin releasing hormone analog combined treatment increased pubertal height gain and adult height in two children who entered puberty with short stature*, J Pediatr Endocrinol Metab. 2006 Sep; 19(9): 1125-21. Available at https://pubmed.ncbi.nlm.nih.gov/17128560/ .

[18] Nutrients, 2021 Oct; 13(10): 3590. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8538528/

interval" and (2) "While the absolute height increased over time, we noted that the height-to-age percentile did not show an increase over time" (meaning that any increase in height was attributable to the child aging, not due to PediaSure).

40. The Abbott 2018 Study, its follow-up study, and the Abbott 2021 Study all conclusively demonstrate that the PediaSure Clinically Proven Claim, as it relates to increasing height is false and misleading. More disturbingly, it demonstrates that Abbott knew its claims were false, yet continued to deceive the consuming public.

41. Yet the deceptions do not end with the withholding of information detrimental to PediaSure's marketing. Of the six studies to which consumers are directed for clinical evidence of PediaSure's height claims, four of them never even studied increases in height:

- Morales, et al, 1991,[19] studied children with the starvation related illnesses, Marasmus and Kwashiorkor, where wasting was so extensive that the subjects needed to be given PediaSure through a feeding tube in a hospital setting.
- Fisberg, et al, 2002,[20] studied the use of pre-biotics and pro-biotics (none of which are contained in PediaSure Grow and Gain) to alter the gut microbiome of children with severe diarrhea and upper respiratory tract infections. The purpose of the study was to reduce the incidence and duration of sick episodes. Significantly, "subjects were not analyzed for previous growth trajectory at study entry" (i.e. there was no baseline ever established).

[19] Morales, E, et al., *Dietary management of malnourished children with a new enteral feeding,* J Am Diet Assoc 1991; 91: 1233-1238. Abstract available at. https://pubmed.ncbi.nlm.nih.gov/1918741/

[20] Fisberg, M, et al., *Effect of Oral Nutritional Supplementation with or without Synbiotics ion Sickness and Catch-up Growth in Preschool Children*, J Am Diet Assoc 1991; 91: 1233-1238. Available at https://www.researchgate.net/publication/237814938_Effect_of_Oral_Nutritional_Supplementation_with_or_Without_Synbiotics_on_Sickness_and_Catch-up_Growth_in_Preschool_Children.

- Akram, et al, 2000,[21] studied "severely malnourished children" in Pakistan, for short-term treatment of severe malnutrition in hospitalized children in Karachi, Pakistan.
- Ramstack and Listernick, 1991,[22] studied 14 developmentally disabled and physically disabled children (i.e. children with Cerebral Palsy and Down Syndrome) who had "abnormal neurologic patterns that interfere with food consumption." Again, they needed to be given PediaSure via feeding tubes.

In no instance did Abbott ever attempt to mirror the experience of, or the impact of their product upon, average American children.

42. Even the two studies that examined height were themselves quick to point out "major study limitation(s)" such as the absence of a control group. *See* Huynh, *et al.,* 2015, at pp. 19-20[23]. The remaining study, Alarcon, *et al.,* 2003[24], utilized "physician directed nutritional counselling" (p. 210), and noted that "children who experience poor weight gain or growth faltering can experience catch-up growth, during which the child grows more rapidly than usual so that he/she catches up to or toward his/her original growth curve. Catch-up growth is a complex biological phenomenon, ***and the mechanisms underlying catch-up growth are not clearly understood*****"** (emphasis supplied) (p. 215). After disclosing this confounding factor, the researchers did nothing to account for the flaw in their study that due to the "biological

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[21] Akram, D.S., et al., *PediaSure in the Treatment of Severe Malnutrition in Pakistani Children*, JPMA 2000; 50: 377-80. Available at Akram, et al. 2000.pdf..

[22] Ramstack M., Listernick R., *Safety and Efficacy of a New Pediatric Enteral Product in the Young Child*, JPEN 1991; 15: 89-92. Available at Ramstack et al. 1991.pdf.

[23] Huynh, D.T.; et al., *Longitudinal growth and health outcomes in nutritionally at-risk children who received long-term nutritional intervention*. J. Hum. Nutr. Diet. 2015, 28, 623–635. Available at Huynh, et al. 2015.pdf.

[24] Alarcon PA, et al., *Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters*. Clinical Pediatrics. 2003;42(3):209-217. doi:10.1177/000992280304200304. Available at Alarcon, et al. 2003.pdf.

phenomenon" of catch-up growth, PediaSure was not able to empirically demonstrate any increase in height due to consumption of its product.

43. This candid self-assessed limitation renders the study little more than a *post hoc ergo propta hoc* ("after the fact therefore because of the fact") fallacy of reason, namely that there was increased height and PediaSure was consumed. Abbott never contemplated that growth in height is attributable to the fact that the child was simply older than at the beginning of the study. This phenomenon was identified, but not causally recognized in the later Abbott 2021 Study: "***While the absolute height increased over time, we noted that the height-to-age percentile did not show an increase over time***". This means that any increase in height was attributable to the child aging, not due to PediaSure. This on top of the fact that the 90-day study was only half as long as the later Abbott 2021 Study which mandated that the minimum study period necessary to assess height growth should be six months: "As a limitation, the 3-month study interval was sufficient to observe catch-up growth in weight; however, the intervention interval should be longer, e.g., 6 months or more, to promote and observe catch-up growth in height." (p 11).[25]

44. Additionally, none of the studies observed subjects for the months or years prior to the study commencement, so there was never any meaningful baseline established for each individual's growth in height history. One non-Abbott funded study (Lampl, *et al*. 2016)[26] specifically criticized the PediaSure studies for this deficit. PediaSure's assertion that it is "Clinically proven to help kids grow" was found to be medically and scientifically unsound, in

[25] Khanna, D, et al., *supra* note 18, at 11.

[26] Lampl, M, et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*, Healthcare (Basel). 2016 Nov 12;4(4):84. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198126/

that it did not "specify just what group of 'kids' were studied, e.g. their initial conditions and growth status prior to intervention." (p. 5).

45. Stated otherwise, there is no mechanism by which Abbott could establish that the subjects experienced an increase in "Height Velocity ("HV")," when they never ascertained that value pre-intervention.

46. Nor was any consideration given to the well understood fact that independent of any nutritional intervention, children do not stay in the same size percentiles, and growth in height is not a linear function. In fact, "more than 70% cross percentile lines in height for weight" (Lampl, p. 8).

47. Lampl, in reviewing the PediaSure studies, goes on to establish that the studies, apart from their inherent confirmation bias as Abbott funded with Abbott employees as lead researchers, establish nothing. "One might suggest that this collection of studies fails to provide robust proof of principle **on any point**, suffering from sub-optimum design due to biased samples, absent or inadequate controls, and questionable criteria for outcome assessment. **Thus, causality cannot be identified even in these clinically growth-impaired children, much less be extended to normal children**" (Lampl p 6, emphasis supplied).

IV. Plaintiff Purchased PediaSure.

48. Beginning in or about January 2022, Plaintiff purchased PediaSure Grow and Gain Vanilla and Strawberry drinks for her eight-year-old grandson for whom Plaintiff was the primary caregiver. Plaintiff's grandson was short for his age and Plaintiff was led to believe that PediaSure would help her grandson get taller by Abbott's Clinically Proven Claim on the PediaSure website and packaging. In February 2023, after a year of taking two PediaSure drinks per day, Plaintiff's grandson was still short for his age but had also become so overweight that Plaintiff discontinued buying PediaSure.

49. Prior to purchasing the PediaSure Products, Plaintiff was exposed to Abbott's on-line marketing of its Clinically Proven Claim and the PediaSure packaging.

50. Plaintiff purchased the PediaSure Products reasonably believing that they were clinically proven to increase height.

51. Plaintiff's grandson did not increase his height-for-age or height-to-weight even after a year of drinking PediaSure.

52. Had Plaintiff known that the PediaSure Products were not clinically proven to achieve increased height, she would not have purchased them. At the very least, Plaintiff would not have paid the price premium charged for PediaSure Products that purported to have been clinically proven to increase height.

53. Plaintiff could have purchased equivalent and less expensive meal replacement drinks for her grandson without the false Clinically Proven Claim hype. For example, instead of the PediaSure drinks that cost $1.92/8 oz. bottle, Plaintiff could have purchased Carnation Breakfast Essentials which have virtually the same nutritional ingredients as the PediaSure Products but cost just $1.29/8 oz. container.

CLASS DEFINITION AND ALLEGATIONS

New York Class

54. Plaintiff brings this action on behalf of herself and all other similarly situated consumers in the State of New York pursuant to Rule 23 of the Federal Rules of Civil Procedure, and seeks certification of the following subclass (the "New York Class"):

> All consumers who, within the applicable statute of limitations period, purchased in the State of New York (whether online or in-person) PediaSure Products – manufactured, marketed, distributed and/or sold by Defendant which Defendant warranted as being "Clinically Proven to help kids grow" (the "Class Products"). Excluded from the class are Defendant, its parents, subsidiaries, affiliates, officers and directors, judicial officers and their immediate family members and associated court staff assigned to this case, and those who purchased Class Products for resale.

55. Plaintiff expressly disclaims any intent to seek any recovery in this action for personal injuries that she or any New York Class member may have suffered.

56. **Numerosity**. This action is appropriately suited for a class action. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed, believes, and thereon alleges, that the proposed Class contains thousands of purchasers of the Class Products who have been damaged by Abbott's conduct as alleged herein. The precise number of the Class members is unknown to Plaintiff but is believed to be in the thousands.

57. **Existence and Predominance of Common Questions of Law and Fact**. This action involves questions of law and fact common to the Classes. The common legal and factual questions for the New York Class include, but are not limited to, the following:

- Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 349.
- Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 350.

- Whether Defendant labeled, advertised, marketed, and/or sold each Class Product as "clinically proven" to cause and maintain height gain.

- Whether Defendant's labeling, advertising, marketing, and/or selling of each Class Product as clinically proven to cause and maintain height gain was and/or is false, fraudulent, deceptive, and/or misleading.

58. **Typicality**. Plaintiff's claims are typical of the claims of the members of her Class, because, *inter alia*, all the Class members have been injured through the uniform misconduct described above and were subject to Abbott's blatant misrepresentations of material information. Moreover, Plaintiff's claims are typical of her Class members' claims. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of her Class.

59. **Adequacy of Representation**. Plaintiff will fairly and adequately protect the interests of the members of her Class. Plaintiff purchased a Class Product, and she was harmed by Abbott's deceptive misrepresentations. Plaintiff has therefore suffered an injury in fact as a result of Abbott's conduct, as did all members of her Class who purchased Class Products. Plaintiff has retained counsel who are adept, sophisticated, and experienced in the field of class action litigation, and have adequate resources to fully and zealously advocate on behalf of the class.

60. **Superiority**. A class action is superior to other methods for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Abbott. It would be virtually impossible for a member of the Class, on an individual basis, to obtain effective redress for the wrongs done to him or her. Further, even if the members of the Class could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized

litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no management difficulties under the circumstances here.

61. Plaintiff seeks monetary damages, including statutory damages on behalf of the Class. Unless the Class is certified, Abbott will be allowed to profit from its deceptive practices, while Plaintiff and the Class will have suffered damages.

COUNT I
(New York Class - Violation of New York General Business Law Section 349)

62. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 through 61 as if fully set forth herein.

63. New York General Business Law § 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York]."

64. By labeling, advertising, marketing, distributing, and/or selling each Class Product to Plaintiff and the other Class members as "Clinically proven to help kids grow" Abbott engaged in, and continues to engage in, deceptive acts and practices because the Class Products are not, in fact, clinically proven to help kids grow in height.

65. In taking these actions, PediaSure failed to disclose material information about its products, which omissions were misleading in a material respect to consumers and resulted in the purchase of PediaSure's products.

66. PediaSure has deceptively labeled, advertised, marketed, promoted, distributed, and sold the Class Products to consumers.

67. PediaSure's conduct was consumer oriented.

68. PediaSure engaged in the deceptive acts and/or practices while conducting business, trade, and/or commerce and/or furnishing a service in New York.

69. PediaSure's misrepresentations were misleading in a material respect as to whether the efficacy of each Class Product is clinically proven.

70. PediaSure knew, or should have known, that by making the misrepresentations addressed herein, Plaintiff and other consumers would be misled into purchasing PediaSure's Products and/or paying a premium price for the PediaSure Products.

71. Plaintiff and the Class members have been aggrieved by and have suffered losses as a result of Abbott's violations of Section 349 of the New York General Business Law. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce, Plaintiff and the members of the Class have been substantially injured by purchasing and/or overpaying for a product that is not what Abbott represents it to be.

72. By reason of the foregoing, Abbott's conduct, as alleged herein, constitutes deceptive acts and practices in violation of Section 349 of the New York General Business Law, and Abbott is liable to Plaintiff and the Class for the actual damages that they have suffered as a result of Abbott's actions, the amount of such damages to be determined at trial, plus statutory damages, treble damages, and attorneys' fees and costs.

73. Abbott's conduct, as alleged herein, in violation of Section 349 of the New York General Business Law was engaged in by Abbott willfully and/or knowingly. Accordingly, Plaintiff and members of the Class are entitled to an award of damages above and beyond their actual damages in accordance with Section 349(h) of the New York General Business Law.

COUNT II

(New York Class - Violation of New York General Business Law Section 350)

74. Plaintiff Noriega realleges and incorporates by reference the allegations in paragraphs 1 through 73 as if fully set forth herein.

75. Abbott's labeling, marketing, and advertising of the Class Products is "misleading in a material respect," as it fails to disclose to consumers material information in Abbott's sole possession and, thus, is "false advertising."

76. No rational individual would purchase the Class Products at the premium prices at which they are sold in full knowledge that they are not clinically proven to increase height, which is how Abbott markets the Class Products.

77. Abbott's advertisements and marketing of the Class Products as "Clinically proven to help kids grow" were consumer oriented.

78. Abbott's advertisements and marketing of the Class Products as "Clinically proven to help kids grow" were misleading in a material respect.

79. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce in New York, Plaintiff and the members of the Class have been substantially injured by overpaying for a product that has diminished value due to its false claim of being "clinically proven."

80. Abbott's conduct, as alleged herein, constitutes false advertising in violation of Section 350 of the New York General Business Law, and Abbott is liable to Plaintiff and the members of the Class for the actual damages that they have suffered as a result of Abbott's actions, the amount of such damages to be determined at trial, statutory damages, plus treble damages, and attorneys' fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against Abbott as follows:

A. Certifying this action as a class action, pursuant to FRCP 23, comprised of the Class as defined above as soon as practicable, designating Plaintiff as the named Class representative and designating the undersigned as Class Counsel.

B. On Plaintiff's Count I, awarding against Abbott the damages that Plaintiff and the other members of the Class have suffered as a result of Abbott's actions, the amount of such damages to be determined at trial, plus statutory damages and treble damages.

C. On Plaintiff Count II, awarding against Abbott the damages that Plaintiff and the other members of the Class have suffered as a result of Abbott's actions, the amount of such damages to be determined at trial, plus statutory and treble damages.

D. On Counts I and II, awarding Plaintiff and the Class interest, costs, and attorneys' fees.

E. Awarding Plaintiffs and their respective class such other and further relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand trial by jury on all issues so triable.

Dated: May__, 2023
White Plains, New York

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